

Application No.: 09/995,938

9

Docket No.: 532792001400

REMARKS/ARGUMENTS

In an Office Action dated February 17, 2004, claims 1-23 were rejected, and claims 25 and 26 were objected to. By this amendment, claims 1, 6-11, 13-14, 17-20, and 22-23 have been amended. Claims 24 and 27 are canceled. Claims 1-23 and 25-26 remain pending. Applicants request reconsideration of the pending claims in view of the present amendment and following remarks. The specification has been amended to remove hyperlinks.

Prior Art

Applicants thank the Examiner for noting that the claims are free from prior art.

Specification

The Examiner objected to the specification as having hyperlinks embedded in the specification. Applicants have amended the specification to remove the "www" at the beginning of the URLs. Thus, the specification no longer includes a hyperlink or other form of browser executable code. Applicants therefore request that the Examiner withdraw the objection.

Claim Objections

The Examiner has objected to claims 6, 7, 13, 14, 22 and 23 as reading on non-elected inventions. The claims have been amended accordingly.

The Examiner has further objected to claims 9-11, 12, 18-20, 22, 25, and 26. Given that the suggested amendments do not alter the scope of the claims, the applicants have amended the claims as suggested by the Examiner.

Claim Rejections – 35 USC § 112, second paragraph

The Examiner has rejected claims 8-17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. Applicants respectfully disagree with the Examiner's grounds for rejection. One of skill in the art would have no difficulty in recognizing the scope of the term "homology." However, in order to facilitate prosecution in this case applicants have amended the

. sf-1694546

Application No.: 09/995,938

10

Docket No.: 532792001400

pending claims, without prejudice or disclaimer, to replace "homology" with "identity", as suggested by the Examiner. Applicants respectfully request that the Examiner withdraw the definiteness rejection.

Claim Rejections – 35 USC § 112, first paragraph, Written Description

The Examiner has rejected claims 1-5, 8-12, and 15-21 under 35 U.S.C. 112, first paragraph, as containing subject matter not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention. The Examiner has asserted that the specification does not adequately disclose the structural features common to members of the claimed genus of polynucleotides.

Applicants respectfully disagree. The specification provides ample discussion of the structural aspects of the claimed invention sufficient to convey to one of skill in the art that the inventors had possession of the claimed invention. In fact, the specification provides more disclosure than in an example provided by the USPTO as a guideline for when the written description has been met. The USPTO has published those guidelines in a document providing specific examples of application of the written description – "SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES". (Available online at: <http://www.uspto.gov/web/menu/written.pdf>). The SYNOPSIS has an example that is very similar to the present situation. Example 9, pages 35-37, (the "SYNOPSIS EXAMPLE") covers hybridization claims that would cover a similar scope as the 80% identity as in the pending claims. In the SYNOPSIS EXAMPLE, only a single cDNA is disclosed, while applicants disclose four cDNAs, SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:9 (and the corresponding polypeptide sequences, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, and SEQ ID NO:10) all of which have the claimed function – producing a genetically modified plant having increased size as compared to a wild-type plant. The SYNOPSIS EXAMPLE states that, "The Art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing." (SYNOPSIS at page 36) At the time of filing of the instant application, sequencing and determining percent identity were well known. Applicants claims are drawn to a genus of nucleic acids all of which must encode a polypeptide with an amino

sf-1694546

Application No.: 09/995,938

11

Docket No.: 532792001400

acid sequence at least 80 % identical to SEQ ID NO:6 and must encode a protein with a specific activity very similar to the SYNOPSIS EXAMPLE. The Examiner has indicated that the prior art fails to teach or suggest an isolated nucleic acid of SEQ ID NO:1 just as in the SYNOPSIS EXAMPLE. Applicants disclose four species that are within the scope of the claimed genus and therefore have actual reduction to practice of four disclosed species which is more than in the SYNOPSIS EXAMPLE. The SYNOPSIS EXAMPLE states, "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since the highly stringent hybridization conditions in combination with the coding function of the DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention." (SYNOPSIS pages 36-37). In the present case, applicants clearly have adequately described the claimed invention and had possession of the invention as of filing the application. Furthermore, one of skill in the art can align the four sequences to identify regions of homology. Such alignments, which are described in the specification from page 10, line 21 to page 12, line 16, are therefore implicit in the disclosure of the specification. One of skill in the art would recognize that the regions of higher homology are more likely to have a conserved function and therefore represent the structural elements that relate to the claimed function. Thus, there is a clear relationship between the structure and the function of the claimed invention that meets the Written Description Requirement. Applicants therefore respectfully request that the Examiner withdraw the rejection.

Claim Rejections – 35 USC § 112, first paragraph, Enablement

The Examiner has rejected claims 1-23 under 35 U.S.C. 112, first paragraph, as failing to enable one of skill in the art to make and use the claimed invention commensurate in scope with the claims.

Applicants respectfully disagree. The specification provides more than adequate support to enable one of skill in the art to make and use the claimed invention commensurate in scope with the claimed invention. The Examiner has asserted that undue experimentation would be required. However, as indicated in *In re Wands*, undue experimentation is evaluated based upon eight factors,

sf-1694546

Application No.: 09/995,938

12

Docket No.: 532792001400

including the quantity of experimentation, the amount of direction or guidance provided, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. In the present application, undue experimentation is not required for one of skill in the art to make and use the invention commensurate in scope with the claims. Application of the *Wands* factors to the claimed invention clearly supports this. The first *Wand* factor is the quantity of experimentation necessary. The quantity of experimentation is not undue. The molecular biology techniques for generating the vectors are routine and therefore not undue experimentation. The techniques for plant transformation are also routine and therefore not undue experimentation. Finally, screening for the claimed function of enlarged plants is routine and therefore not undue experimentation. It does not matter that it may take a fair amount of work to screen through multiple non-exemplified sequences to find those that function. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. All of the construct generation and testing is routine in the art.

The second *Wands* factor is the amount of direction or guidance provided. As discussed with regard to the first *Wands* factor, the nature of the experimentation is all routine, so the techniques used need not be disclosed, and yet they are disclosed in actual working examples. Furthermore, page 10, line 21 to page 12, line 16, discusses routine methods of alignment of nucleic acid and protein sequences. Such alignments can provide information regarding the structural elements that are likely required for function and will indicate some of the mutations that may be accommodated without affecting the function. Thus, there is a fair amount of guidance provided as to what sequences are likely to work including three that actually work and additional guidance as to how such sequences may be modified.

The third *Wands* factor is the present or absence of working examples. Applicants have taught three nucleic acid molecules encoding polypeptides that exhibit at least 80% sequence identity to SEQ ID NO:6. As shown in Example 8 on page 37, lines 21-22, overexpression of the wild type BRZ1 gene led to slightly increased hypocotyl and petiole elongation. This slight

sf-1694546

Application No.: 09/995,938

13

Docket No.: 532792001400

increase is sufficient to meet the utility requirement and therefore sufficiently enables one of skill in the art to make and use the claimed invention. Furthermore, expression of brz1-D and brz2-D lead to increased cell elongation as shown on page 37, lines 22-26 of the specification. Thus the applicants have provided several working examples.

The fourth *Wands* factor is the nature of the invention. In this case, making and using the invention requires only routine techniques and is a matter of routine testing of sequences related to those disclosed.

The fifth *Wands* factor is the state of the prior art. The state of the art is high. As of the priority date of November 27, 2001, molecular biology techniques were well worked out and included a high degree of automation owing to genome sequencing, etc. Thus, one of skill in the art is capable of screening through large numbers of random and site-directed mutants.

The sixth *Wands* factor is the relative skill of those in the art. The skill in the art is quite high. Plant transformation is typically done by graduate level research scientists or higher.

The seventh *Wands* factor is the predictability or unpredictability of the art. While the effect of mutations in genes cannot be predicted with one hundred percent accuracy, the working examples combined with sequence alignments provides some degree of predictability that will provide one of skill in the art a starting point.

The eighth *Wands* factor is the breadth of the claims. As discussed above in the SYNOPSIS EXAMPLE provided by the USPTO, one of skill in the art would not expect substantial variation under high stringency hybridization conditions and 80% identity is similarly constrained. Therefore the breadth of the claims is not unduly broad.

Thus given that most if not all of the *Wands* factors weigh in the favor of the applicants, the invention as claimed would not require undue experimentation by one of skill in the art to make and use the invention commensurate with the scope of the invention. Applicants respectfully request that the Examiner withdraw the Enablement rejection.

sf-1694546

Application No.: 09/995,938

14

Docket No.: 532792001400

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no.

532792001400. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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sf-1694546